

August 3, 2005

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**Re: Guidance on Temporary Variances for Research 205.209(a) (3); NOSB Policy Development Committee agenda, August 15, 2005**

Dear Dave,

On behalf of the Organic Farming Research Foundation, I thank you for bringing forward the draft recommendation (July 13, 2005) for "Guidance on Temporary Variances for Research Studies." As you know, OFRF has funded numerous organic research projects over the years, and we have proposed various guidelines and criteria for the design and management of organic research activities.

As the document correctly notes, there has been significant growth in organic research assets and capacities around the U.S., and certification of these research settings is very important for several reasons. Appropriate application of the National Organic Regulation to research activities does require careful consideration about variances that might be granted under Sec. 205.209(a)(3).

We see an excellent basis in this draft for forward progress, a lot of material for constructive discussion, and some flaws that need to be corrected. To assist the Board's August 15 discussion on the current draft recommendations (dated July 13), we submit the following comments, organized under the document's section headings:

**Introduction**

While most of this text is quite cogent, it does not examine certain distinctions that appear to be critical in the draft recommendations. Specifically, 1) the distinction between products that may or may not enter the stream of commerce; and 2) the distinction between crops and livestock production. The draft recommendations are formed differently for these cases, but the Introduction does not explain the rationales or considerations that give rise to these different protocols. These distinctions are also made in the Q&A section, but the (implicit) rationales are not completely clear to us. The Committees should explain exactly why and how these differences are perceived to be meaningful in the context of temporary research variations.

Another distinction that is not specifically reflected in the recommended guidance, but perhaps should be, is the difference between research conducted on working farms vs. research stations. This does not necessarily correspond with the “stream of commerce” distinction, but it seems related. Has the Committee considered the outcomes of its recommendation in cases where the research setting is not a dedicated research plot?

A more challenging distinction that should be examined carefully is the difference between proprietary research and that conducted in the public domain. The Introduction notes that the regulation does not limit the provision for research variances to only University settings, but the discussion and the Q&A still seem to assume that public-domain science is the context at hand. Has the Committee looked at the application of temporary research variances in pursuit of private, proprietary research, located on private, certified operations? Do the Committee’s assumptions about research outcomes (e.g., “providing data and knowledge”) still hold in these situations?

### Discussion

The three criteria established in this section for research that may qualify for a variance are a great start for developing the recommendations. Further discussion of these criteria will be very constructive. This statement of criteria should also stress the temporary and exceptional nature of variances. They should not be expected to become routine, *de facto* modifications of the regulation.

The first criterion (“Must follow the scientific method”) begs for a definition. Does “scientific method” mean simply a process of formulating and testing a hypothesis? Or does it imply “a factorial experiment with no-treatment controls to prove a null hypothesis?” If this criterion is to be usefully applied, it must be defined more precisely. Beyond the meaning of the phrase, the committee’s precise intent in applying this criterion is not clear. Although it may seem obvious, the Committee should explain why it deems this to be imperative.

The second item (i.e., provides information that is valid in the context of organic systems) is crucial in justifying a request for a variance. However, it begs the question of “providing data and knowledge” for whom? Is there an assumption here that proprietary research should only qualify for variances if the data is made public?

The third item (i.e., must protect the site’s organic integrity) is equally important. However, it is a criterion that should be applied to the variance itself, rather than the “research project.” In other words, it should be clearly stated that granting a variance *must not compromise the organic integrity of the site or its validity as a location for bona fide organic research.*

### Recommendation

We wish to note several specific concerns with the draft recommendation, with special emphasis on item A.3) and item E.:

-As stated above, the precise rationale is not apparent for distinguishing variance protocols based on product marketing (or not). While we generally expect that products harvested from ground on which a temporary research variance has been granted *could* still be validly sold as organically produced (as implied by criteria 2 and 3 in the Discussion section), we are not sure if they *should* be sold as such. There are concerns about fairness to other growers as well as consumers that should be part of this discussion. What are the Committees assumptions about these scenarios? Are these assumptions based on data or anecdotal information? We suspect that more information about the commercial fate of products from research activities (i.e., frequency, quantities and market channels) is needed.

-Parts A.1), B.1) and D.1) should all substitute the phrase “experimental design” for “scientific method.” (See comments on this topic above). This would be more germane to consideration of the request.

**-Part A. 3)** of the recommendation implies that a variance could be granted for the application of otherwise prohibited materials. However, Sec. 205.290 does not allow for variances from Sec. 205.105. As we read it, there can be no variances for the application of prohibited materials, regardless of whether the products are marketed as organic. Therefore, this section of the recommendation does not make sense. Even if this were not the case, we do not agree that variances ought to be granted for application of synthetic materials in order that comparisons between organic and “pest free” production can be made on certified organic research ground. The objectives of “comparative” studies may be worthwhile, but they do not justify compromising the integrity of certified ground, either on a research station or a working farm.

-Part C. is not clear as to the nature of the Administrator’s action. Would it be one action for all certifiers? Part of each certifier’s accreditation? On what time interval would the Administrator issue this authorization?

-Part D. in several sections is again problematic with respect to the expectation that variances could be granted for “substances” (see above).

**-Part E.** is crucial to the effectiveness of this entire guidance. We strongly support this provision, but we believe it is necessary to add the following sentence: *“The Administrator shall make this information available to the NOSB and the public.”* Full transparency of the temporary variance process is essential for further refinement, and to ensure continued integrity of scientific research for organic agriculture.

### Questions and Answers

Several of the points we have raised in previous sections are also related to the details of this section. There is one point we wish to note that has not been raised above:

-Question 7) suggests a reverse scenario to be pursued by researchers. Rather than “animal welfare review committee approval of experimental protocols” being accepted as adequate for organic livestock research, we suggest that the compliant organic management plan be accepted as adequate for ensuring animal welfare to animal welfare review committees.

Thank you for your consideration of our comments. We look forward to further constructive discussion.

Organically Yours,

*//Mark Lipson//*

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